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PTO/SB/21 (09-04)

Approved for use through 07/31/2008. OMB 0651-0031

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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

9

Application Number

10/678,379

Filing Date

October 6 2003

First Named Inventor

Donald R. VanDeripe

Art Unit

3743

Examiner Name

Mital B. Patel

Attorney Docket Number

ENCLOSURES (Check all that apply)

Fee Transmittal Form



Fee Attached



Amendment/Reply



After Final



Affidavits/declaration(s)



Extension of Time Request



Express Abandonment Request



Information Disclosure Statement



Certified Copy of Priority Document(s)

Reply to Missing Parts/
Incomplete ApplicationReply to Missing Parts
under 37 CFR 1.52 or 1.53

Drawing(s)



Licensing-related Papers



Petition

Petition to Convert to a
Provisional Application

Power of Attorney, Revocation



Change of Correspondence Address



Terminal Disclaimer



Request for Refund



CD, Number of CD(s) _____



Landscape Table on CD



After Allowance Communication to TC

Appeal Communication to Board
of Appeals and InterferencesAppeal Communication to TC
(Appeal Notice, Brief, Reply Brief)

Proprietary Information



Status Letter

Other Enclosure(s) (please identify
below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

Signature

Donald R. VanDeripe

Printed name

Donald R. VanDeripe

Date

11/03/2005

Reg. No.

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature

Donald R. VanDeripe

Typed or printed name

Donald R. VanDeripe

Date

11/03/2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/17 (12-04v2)

Approved for use through 07/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Effective on 12/08/2004.

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL

For FY 2005

☒ Applicant claims small entity status. See 37 CFR 1.27TOTAL AMOUNT OF PAYMENT (\$)65.00**Complete if Known**

| | |
|----------------------|----------------------------|
| Application Number | <u>10/678,379</u> |
| Filing Date | <u>October 6, 2003</u> |
| First Named Inventor | <u>Donald R. VanDeripe</u> |
| Examiner Name | <u>Mital B. Patel</u> |
| Art Unit | <u>3743</u> |
| Attorney Docket No. | |

METHOD OF PAYMENT (check all that apply)☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____☐ Deposit Account Deposit Account Number: _____ Deposit Account Name: _____

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee☐ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☐ Credit any overpayments

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FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

| Application Type | FILING FEES | | SEARCH FEES | | EXAMINATION FEES | | Fees Paid (\$) |
|------------------|-------------|-----------------------|-------------|-----------------------|------------------|-----------------------|----------------|
| | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | Fee (\$) | Small Entity Fee (\$) | |
| Utility | 300 | 150 | 500 | 250 | 200 | 100 | |
| Design | 200 | 100 | 100 | 50 | 130 | 65 | |
| Plant | 200 | 100 | 300 | 150 | 160 | 80 | |
| Reissue | 300 | 150 | 500 | 250 | 600 | 300 | |
| Provisional | 200 | 100 | 0 | 0 | 0 | 0 | |

2. EXCESS CLAIM FEES**Fee Description**

Each claim over 20 (including Reissues)

Each independent claim over 3 (including Reissues)

Multiple dependent claims

| Fee (\$) | Small Entity Fee (\$) |
|----------|-----------------------|
| | |
| 50 | 25 |
| 200 | 100 |
| 360 | 180 |

| | | | |
|--------------|--------------|----------|---------------|
| Total Claims | Extra Claims | Fee (\$) | Fee Paid (\$) |
| - 20 or HP = | x | = | |

HP = highest number of total claims paid for, if greater than 20.

| | | | |
|---------------|--------------|----------|---------------|
| Indep. Claims | Extra Claims | Fee (\$) | Fee Paid (\$) |
| - 3 or HP = | x | = | |

HP = highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

| | | | | |
|--------------|--------------|--------------------------------------------------|----------|---------------|
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof | Fee (\$) | Fee Paid (\$) |
| - 100 = | / 50 = | (round up to a whole number) x | = | |

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): late file surcharge - Declaration 65.00**SUBMITTED BY**

| | | | |
|-------------------|----------------------------|-----------------------------------|-------------------------------|
| Signature | <u>Donald R. VanDeripe</u> | Registration No. (Attorney/Agent) | Telephone <u>636 477 0322</u> |
| Name (Print/Type) | <u>Donald R. VanDeripe</u> | Date | <u>11/03/2005</u> |

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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11/07/2005 CNGUYEN 00000084 10678379

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65.00 OP



Applicant Initiated Interview Request Form

Application No.: 10/678,379 First Named Applicant: Donald R. VanDeripe
Examiner: Mital B. Patel Art Unit: 3743 Status of Application: Non-final
rejection

Tentative Participants:

(1) Mital B. Patel (2) Donald R. VanDeripe
(3) _____ (4) _____

Proposed Date of Interview: Thurs. Oct 27, 2005 Proposed Time: 5-7 (AM/PM)

Type of Interview Requested:

(1) ☒ Telephonic (2) ☐ Personal (3) ☐ Video Conference

Exhibit To Be Shown or Demonstrated: ☐ YES ☒ NO

If yes, provide brief description: _____

Issues To Be Discussed

| Issues (Rej., Obj., etc) | Claims/ Fig. #s | Prior Art | Discussed | Agreed | Not Agreed |
|-----------------------------|--------------------|---------------------------------------|--------------------------|--------------------------|--------------------------|
| (1) <u>Rej</u> | <u>claim 1</u> | <u>Garrett</u> <u>US 6,001,332</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (2) <u>Rej</u> | <u>claim 2</u> | <u>Garrett</u> <u>US 6,001,332</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (3) _____ | _____ | _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (4) _____ | _____ | _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

☒ Continuation Sheet Attached

Brief Description of Arguments to be Presented:

For both claims; critical differences in formulations, methods of
administration, conditions to be treated, terminology, and concept
of ordinary skill in the art, and myocardial infarction.

An interview was conducted on the above-identified application on October 27th 2005 5PM EDT

NOTE: This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).

This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

Donald R. VanDeripe
Applicant/Applicant's Representative Signature

Examiner/SPE Signature

Donald R. VanDeripe, Ph.D.
Typed/Printed Name of Applicant or Representative

Registration Number, if applicable



11/03/05

Mital B. Patel
Patent Examiner

This communication represents Applicant's formal response to office action signed by Mital B. Patel on 8/7/05 and mailed on 8/9/05 regarding application 10/678,379 filed 10/06/2003.

The following is my understanding of the telephone interview between applicant (Donald R VanDeripe) and examiner (Mital B. Patel) conducted Thursday Oct. 27th 2005 at 5 PM EDT.

Applicant requests examiner's review of comments [A-F] below as they pertain to the allowance of application 10/678,379.

Applicant can be reached at Phone 636 477 0322 or Email donaldvan.1@netzero.net

Issue number 1. Rejection of claim 1 based on Garrett US 6,001,332 under 35 U.S.C 103 -subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Differences between 10/678,379 and Garrett US 6,001,332 which were discussed and actions agreed upon.

[A] Garrett in the DETAILED DESCRIPTION OF THE INVENTION, Col 2 lines 53-67, and all of Columns 3 and 4, and especially in all 12 claims includes carbon dioxide as an obligate component in each of his gas mixtures ranging in concentrations from 1-10%.

Applicant does not include the words carbon dioxide in the specification and states in Claim 1 – wherein the specific gas mixtures consist only as complimentary concentrations of 20-100% oxygen and 0-80% helium.

Clearly, applicant's inclusion of the word -only- defines the use of specific gas formulations consisting only of oxygen and helium and not carbon dioxide and should qualify as a basis for a significant deviation in the composition and use of gas mixtures compared against Garrett.

Action proposed: none needed, the word -only- in Claim 1 suffices.

[B] Methods of Administration: Garrett Col. 1, lines 42-46 and Col. 2, lines 38-44 describes the benefit of self-administration of gases or gas-mixtures by patients. Inherent in any self-administration system is the ability of the patient to

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11/03/2005

remove the mask and talk, thereby breathing ambient air (nitrogen) for a few seconds or minutes. Such actions would completely negate any benefits of 10/678,379 since only a few breaths of air would reverse about 10 minutes of nitrogen washout. As well, Garrett does not indicate anywhere in his specification that exhaled gases need to be shunted to ambient atmosphere, an absolute requirement for achieving nitrogen washout from the body, body water, ischemic tissues and mitochondria as required by applicant's specification [0006 page 4, lines 10-13 and 0010 page 5 lines 1-2]] and Claim 1. Moreover, Garrett does not specify the need to use a one way flutter valve to achieve nitrogen exhalation and washout.

Applicant does not allow self-administration for the above reason that breathing ambient air would allow the inhalation of nitrogen and applicant has specified in the Detailed Description of the Invention [0006] lines 25-27 – Any gas formulation which has as its main purpose the washout of nitrogen from the body would surely be devoid of nitrogen per se.

Action proposed: (amendment) add the phrase- and are devoid of nitrogen.- to the end of claim 1.

[C] Timing of administration and medical supervision.

Garrett's self-administration mode requires patients to be awake, alert and cooperative for successful gas administration. Many or most stroke and heart attack victims are unconscious or under extreme anguish and pain and must therefore be administered gases by a second party, e.g. an emergency medical technician in the transport vehicle and a physician or respiratory therapist at the hospital.

Applicant notes [0007] lines 1-2 This nitrogen washout technique could be started during patient transport or upon admission to the hospital. This statement indicates the need for early intervention to effect the timely washout of nitrogen from the body.

Action proposed: Amend claim 1, after the word implemented insert during patient transport or upon admission to the hospital as quickly as possible.....

[D] Terminology: Key words used to describe Applicant's and Garrett's invention and number of mentions (use terms) in the inventions.

| WORDS | 10/678,793 | Garrett 6,001,332 |
|--------------------------------------|------------|-------------------|
| Nitrogen washout | 23 | 0 |
| Mitochondria | 28 | 0 |
| Stroke | 8 | 0 |
| Carbon dioxide | 0 | 31 |
| Asthma | 0 | 13 |
| MRI (magnetic resonance imaging) | 0 | 11 |
| Heart attack (myocardial infarction) | 4 | 1 |

These tabulations clearly indicate that applicant was focusing on nitrogen washout from mitochondria in strokes and heart attacks, whereas Garrett was primarily directed at administration of gas mixtures all of which contained carbon dioxide for use in treating asthma and for MRI imaging. There is a wide divergence in the goals of these patent specifications.

Action proposed: None required, the listing clearly indicates marked differences in the words that denote the technology and conditions to be treated.

[E] Obviousness Rejection: -obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.

Applicant asserts that 10/678,379 falls outside the above obviousness statement for the following reasons.

Strokes and heart attacks are two of the most aggressively studied health problems in the world, commanding billions of dollars of research funds over the past 40 years and the efforts and expertise of thousands of M.D. and Ph.D. scientists. Their work has been published in numerous scientific journals. Therefore, if Garrett taught a person of ordinary skill in the art that 10/678,379 technology would be of value in treating strokes and heart attacks, then it would have surely taught expert M.D. and Ph.D. scientists that obviousness. Not only has that not been the case, but it is still not apparent to these experts even though Garrett has been available since 12/14/1999. Moreover, applicant's publication in Medical Hypotheses (2004) remains the only mention in the scientific literature on the value of nitrogen washout from the body as a means for treating strokes and heart attacks.

Issue number 2: Rejection of claim 2 based on Garrett US 6,001,332.

[F] Nitrogen washout in heart attacks, Claim 2.

Garrett (6,001,332) does have a single mention (Col. 2, lines 3-7) that a helium oxygen mixture appears to stabilize the myocardium reducing the risk of ventricular arrhythmias in patients who have suffered an acute myocardial infarction.

Applicant contends that this statement is of little relevance since Garrett also indicates (Col. 1 lines 49-50, and 57-58) that helium is an inert gas without any pharmacological activity and that the low solubility of helium prevents any significant absorption into the pulmonary vasculature. These statements would seem to contradict the claim that helium participates in an apparent stabilization of the heart. Moreover, Garrett does not provide any information as to what other gases or drugs may have been employed in such studies. And, the fact that Garrett did not expand on this statement as part of his Detailed Description of the Invention or in his Claims suggests that the Col. 2, line 3-7 comments were made in passing and of little or no importance to his specification.

Applicant claims no specific stabilization of the heart from the use of oxygen helium mixtures. The goal of the nitrogen washout from the body, body water, ischemic tissues, and mitochondria is to allow the reuptake of oxygen into hypoxic mitochondria and restore oxidative metabolism to affected tissues.

Action proposed: Allowance of claim 2 as drafted (amendments to claim 1 are applicable to claim 2.)

PROPOSED NEW READING OF CLAIM 1.

The method of inhalation of specific gas mixtures in a human patient with exhaled gases being shunted into the ambient atmosphere to effect a 50-90% or more washout of nitrogen gas from the body, body water, ischemic tissues, and mitochondria in order to allow the reuptake of oxygen into hypoxic mitochondria and restore oxidative metabolism to affected tissues following reversible vascular occlusions in a cerebrovascular accident (stroke), the administration of said gas mixture being from a suitable supply source and being implemented during patient transport or upon admission to the hospital as quickly as possible following the vascular event and continued for a minimum of 30 minutes up to 72 hours to assure optimum therapy and minimize cell death, wherein the specific gas mixtures consist only as complimentary concentrations of 20-100% oxygen and 0-80% helium and are devoid of nitrogen.

Note: For support of -during patient transport or upon admission to the hospital- see [0007] line 1-2. For support of -devoid of nitrogen- see [0006] next to last line of page 3.

(Correction) Page 2 [0004] line 6. Replace the word Histology with Physiology.

In conclusion, applicant contends that the above arguments and suggested modifications to the wording of Claim 1 traverse examiners objections based on Garrett as a source for obviousness to those with ordinary skill in the art. Consequently, Applicant respectfully requests that 10/678,379 be allowed to issue subsequent to a follow-up telephone review to reach agreement as to appropriate wording for amendments to Claim 1.

Thank you for your assistance in this matter.



Donald R. VanDeripe, Ph.D.
1534 Woodbury Drive
St. Charles, Mo 63304

DLV
11/03/05